

Brussels, 5 July 2024
Case No: 92186
Document No: 1461871

ORIGINAL

IN THE EFTA COURT

WRITTEN OBSERVATIONS

submitted, pursuant to Article 20 of the Statute of the EFTA Court, by the

THE EFTA SURVEILLANCE AUTHORITY

represented by
Kyrre Isaksen, Sigrún Ingibjörg Gísladóttir
and Melpo-Menie Josephides,
Department of Legal & Executive Affairs,
acting as Agents,

IN CASE E-8/24

Nordsjø Fjordbruk AS

v

The Norwegian State

in which the Referring Court asks the EFTA Court if Regulation (EU) 2016/429 must be interpreted as precluding the central veterinary authorities of the EEA States from prohibiting the movement of farmed fish from one aquaculture establishment to another within national borders, or are precluded from refusing to approve an operating plan for an aquaculture establishment, in certain situations.

Table of Contents

1	INTRODUCTION AND FACTS OF THE CASE	3
2	RELEVANT LAW	3
2.1	EEA Law	3
2.2	NATIONAL LAW	8
3	THE QUESTIONS REFERRED	10
4	ESA'S SUBMISSIONS.....	11
4.1	Introduction	11
4.2	Analysis	13
4.2.1	Prohibiting the movement of aquaculture animals between establishments	13
4.2.2	Refusal to approve an operating plan	16
5	CONCLUSION.....	18

1 INTRODUCTION AND FACTS OF THE CASE

1. The present case is a request for an Advisory Opinion (“**the Request**”) from the Supreme Court of Norway (“**the Referring Court**”) concerning the interpretation of Regulation (EU) 2016/429 on transmissible animal diseases (Animal Health Law)¹ (“**the Regulation**”), and in particular Articles 9, 10, 176, 181, 183-184, 191-192, 226 and 269 thereof. More specifically the case concerns whether the Regulation precludes national competent authorities to prohibit movements of farmed fish between aquaculture establishments within national borders where there is no detected disease or concrete suspicion of disease in the fish, but where the competent authority, following a specific assessment, has found that considerations of fish health warrant such a prohibition.
2. The Regulation is an overarching legal framework that lays down general and specific rules for the prevention and control of infectious animal diseases across sectors to ensure a harmonised approach to animal health. Pursuant to its Article 1(2)(a) the aim of the Regulation is to ensure high standards of animal and public health in the EEA, effective functioning of the internal market and to avoid the spread of infectious diseases. The regulation covers both terrestrial and aquatic animals and their products.²
3. For details about the facts of the case, reference is made to the Request.

2 RELEVANT LAW

2.1 EEA Law

4. The relevant recitals of the Regulation provide:

(1) The impact of transmissible animal diseases and the measures necessary to control those diseases can be devastating for individual animals, animal populations, animal keepers and the economy. [...]

¹ OJ L 84, 31.3.2016, p. 1. Incorporated into the EEA Agreement (“EEA”) by Decision of the EEA Joint Committee No 179/2020 of 11 December 2020, OJ L 240, 28.9.2023, p. 5. Compliance date in the EEA was 21.4.2021.

² To ESA’s knowledge, this is the first case before the EFTA Court or the Court of Justice concerning the interpretation of the Regulation.

(8) The Commission's communication of 19 September 2007 on a new Animal Health Strategy for the European Union (2007-2013) where 'Prevention is better than cure' aims to promote animal health by placing greater emphasis on preventive measures, disease surveillance, disease control and research, in order to reduce the incidence of animal diseases and minimise the impact of outbreaks when they do occur.

(9) The aim of this Regulation is to implement the commitments and visions provided for in that Animal Health Strategy, including the 'One health' principle, and to consolidate the legal framework for a common Union animal health policy through a single, simplified and flexible regulatory framework for animal health. [...]

(15) The risk assessment on the basis of which the measures under this Regulation are taken should be based on the available scientific evidence and undertaken in an independent, objective and transparent manner. Due account should also be taken of the opinions of the European Food Safety Authority (EFSA) established by Article 22(1) of Regulation (EC) No 178/2002 of the European Parliament and of the Council.[...]

(18) Diseases occurring in animals which are kept by humans can have severe impacts on the agriculture and aquaculture sectors, on public health, on the environment and on biodiversity. However, as such animals are kept by humans, disease prevention and control measures are often easier to apply to them than to wild animals. [...]

(20) Animal diseases are not only transmitted through direct contact between animals or between animals and humans. They are also carried further afield through water and air systems, vectors such as insects, or the semen, oocytes and embryos used in artificial insemination, oocyte donation or embryo transfer. [...] Moreover, various other objects such as transport vehicles, equipment, fodder and hay and straw may diffuse disease agents. Therefore, effective animal health rules need to cover all paths of infection and material involved therein. [...]

(136) The registration and approval of aquaculture establishments is necessary in order to allow the competent authority to perform adequate surveillance and to prevent, control and eradicate transmissible animal diseases. Directive 2006/88/EC requires all establishments which move aquatic animals to be authorised. That system of authorisation should be maintained under this Regulation, notwithstanding the fact that, in some official languages of the Union, this Regulation uses different terms to refer to the authorisation system from those used in Directive 2006/88/EC. [...]

(146) To encourage Member States to enhance the health status of their aquatic populations, certain adjustments and added flexibility should be introduced in this Regulation.

(149) Union aquaculture production is extremely diverse as regards species and production systems, and this diversification is rapidly increasing. This may require the adoption at Member State level of national measures concerning diseases other than those regarded as listed diseases in accordance with this Regulation. However, such national measures should be justified, necessary and proportionate to the goals to be achieved. Furthermore, they should not affect movements between Member States unless they are necessary in order to prevent the introduction, or to control the spread, of disease. National measures affecting trade between Member States should be approved and regularly reviewed at Union level.

(165) This Regulation lays down general and specific rules for the prevention and control of transmissible animal diseases and ensures a harmonised approach to animal health across the Union. In some areas, such as general responsibilities for animal health, notification, surveillance, registration and approval or traceability, the Member States should be allowed or encouraged to apply additional or more stringent national measures. However, such national measures should be permitted only if they do not compromise the animal health objectives set out in this Regulation and are not inconsistent with the rules laid down herein, and provided that they do not hinder movements of animals and products between Member States, unless this is necessary in order to prevent the introduction, or to control the spread, of disease.

5. Articles 10(1) and (4) of the Regulation provides:

1. *Operators shall:*

(a) *as regards kept animals and products under their responsibility, be responsible for:*

(i) *the health of kept animals;*

(ii) *prudent and responsible use of veterinary medicines, without prejudice to the role and responsibility of veterinarians,*

(iii) *minimising the risk of the spread of diseases;*

(iv) *good animal husbandry;*

(b) *where appropriate, take such biosecurity measures regarding kept animals, and products under their responsibility, as are appropriate for:*

(i) *the species and categories of kept animals and products;*

(ii) *the type of production; and*

(iii) *the risks involved, taking into account:*

— *geographical location and climatic conditions; and*

— *local circumstances and practices;*

(c) *where appropriate, take biosecurity measures regarding wild animals.*

[...]

4. *The biosecurity measures referred to in point (b) of paragraph 1 shall be implemented, as appropriate, through:*

(a) *physical protection measures, which may include:*

(i) *enclosing, fencing, roofing, netting, as appropriate;*

(ii) *cleaning, disinfection and control of insects and rodents;*

(iii) *in the case of aquatic animals, where appropriate:*

— *measures concerning the water supply and discharge;*

— *natural or artificial barriers to surrounding water courses that prevent aquatic animals from entering or leaving the establishment concerned, including measures against flooding or infiltration of water from surrounding water courses;*

(b) *management measures, which may include:*

(i) *procedures for entering and exiting the establishment for animals, products, vehicles and persons;*

(ii) *procedures for using equipment;*

- (iii) conditions for movement based on the risks involved;*
- (iv) conditions for introducing animals or products into the establishment;*
- (v) quarantine, isolation or separation of newly introduced or sick animals;*
- (vi) a system for safe disposal of dead animals and other animal by-products.*

9. Article 181(1) of the Regulation provides:

1. The competent authority shall only grant approvals of aquaculture establishments as referred to in Article 176(1) and point (a) of Article 178, groups of aquaculture establishments as referred to in Article 177 and disease control aquatic food establishments as referred to in Article 179, where such establishments:

(a) comply with the following requirements, where appropriate, in relation to:

(i) quarantine, isolation and other biosecurity measures taking into account the requirements provided for in point (b) of Article 10(1)) and any rules adopted pursuant to Article 10(6);

(ii) surveillance requirements as provided for in Article 24, where relevant for the type of establishment concerned and the risk involved, in Article 25;

(iii) record-keeping as provided for in Articles 186 to 188 and any rules adopted pursuant to Articles 189 and 190;

(b) have facilities and equipment that are:

(i) adequate to reduce the risk of the introduction and spread of diseases to an acceptable level, taking into account the type of establishment concerned;

(ii) of a capacity adequate for the species, categories and quantity (numbers, volume or weight) of aquatic animals concerned;

(c) do not pose an unacceptable risk as regards the spread of diseases, taking into account the risk-mitigation measures in place;

(d) have in place a system which enables the operator concerned to demonstrate to the competent authority that the requirements laid down in points (a), (b) and (c) are fulfilled.

10. Article 269 of the Regulation Provides:

1. In addition to what follows from other provisions in this Regulation, allowing the Member States to adopt national measures, Member States may apply within their territories measures that are additional to, or more stringent than, those laid down in this Regulation, concerning:

(a) responsibilities for animal health as provided for in Chapter 3 of Part I (Articles 10 to 17);

(b) notification within Member States as provided for in Article 18;

(c) surveillance as provided for in Chapter 2 of Part II (Articles 24 to 30);

(d) registration, approval, record-keeping and registers as provided for in Chapter 1 of Title I (Articles 84 to 107), and Chapter 1 of Title II, of Part IV (Articles 172 to 190);

(e) traceability requirements for kept terrestrial animals and germinal products as provided for in Chapter 2 of Title I of Part IV (Articles 108 to 123).

2. The national measures referred to in paragraph 1 shall respect the rules laid down in this Regulation and shall not:

(a) hinder the movement of animals and products between Member States;

(b) be inconsistent with the rules referred to in paragraph 1.

2.2 NATIONAL LAW

11. The Regulation has been implemented into the Norwegian legal order by Regulation No 631 of 6 April 2022 on animal health,³ which is adopted on the basis of Act No 124 of 19 December 2003 of food production and food safety (the Food Act).⁴

12. Section 19 of the Norwegian Food Act provides, in relevant parts:

Everyone must exercise the necessary care, so that there is no risk of the development or spread of infectious animal disease.

³ Forskrift om dyrehelse (dyrehelseforskriften), FOR-2022-04-06-631.

⁴ Lov om matproduksjon og mattrygghet mv. (matloven), LOV-2003-12-19-124.

Live animals must not be traded, taken into animal husbandry, moved or released when there is reason to suspect an infectious animal disease that could have significant social consequences. [...]

13. Section 40 of Regulation No 822 of 17 June 2008⁵ on the operation of aquaculture facilities provides:

There must be an operating plan for aquaculture facilities in seawater at all times. In the case of joint operation, there must be a joint operating plan.

For the next two calendar years, the operating plan must at least state:

- a. which locations it is planned to release fish, the time of release and the number of fish. For localities where several aquaculture permits are attached, it must be stated which permits the postponement applies to, and*
- b. time period for fallowing and possible storage of cleaning fish and moving fish to other locations, and*
- c. which locations are possibly not planned to be used.*

Locations in seawater with food fish and breeding fish must be emptied and left fallow for a minimum of 2 months after each production cycle. This does not prevent cleaning fish from being stored on the site if this is justifiable from the point of view of contamination. The Norwegian Food Safety Authority can decide on a longer set-aside period for the individual locality and coordinated set-aside of an area for reasons of fish health.

Operation and fallowing must take place in such a way that all locations in an area are utilized as efficiently as possible to achieve increased value creation. The Directorate of Fisheries can decide on a longer set-aside period for the individual locality or coordinated set-aside of an area for environmental reasons.

The operation plan for food fish and broodstock of salmon, trout, rainbow trout and cod for the next two calendar years must be sent to the Directorate of

⁵ Forskrift om drift av akvakulturanlegg (akvakulturdriftsforskriften). FOR-2008-06-17-822.

Fisheries for approval before 1 October. The requirement for submission and approval does not apply to aquaculture of cod that is based on wild-caught fish.

The Directorate of Fisheries, in consultation with the Norwegian Food Safety Authority, must decide on the approval of the part of the plan that applies to the first year. In a decision, the Norwegian Food Safety Authority can refuse approval if considerations for fish health in the individual locality or in an area so require.

In the event of significant changes in relation to the approved part of the plan, an application for approval of the changes must be sent to the Directorate of Fisheries as soon as possible.

3 THE QUESTIONS REFERRED

14. The Supreme Court of Norway has referred the following question:

Must the Regulation be interpreted to mean that the Central Competent Authorities in the EEA States are precluded from prohibiting the movement of farmed fish from one aquaculture establishment to another one within national borders, or from refusing to approve an operating plan for an aquaculture establishment, in a situation:

- *where there is no detected disease or concrete of suspicion of the disease in the fish,*
- *but the competent authority, following a specific assessment, has found that considerations of fish health at the individual site or in an area warrant such prohibition or refusal.*

4 ESA'S SUBMISSIONS

4.1 Introduction

15. At the outset, the EFTA Surveillance Authority (“**ESA**”) notes that it follows from Article 8(3) EEA that the product coverage of the EEA Agreement does not include fish and other marine products unless otherwise specified.⁶
16. It is provided for in Article 17 EEA that Annex I to the EEA Agreement contains specific provisions and arrangements concerning veterinary and phytosanitary matters. Consequently, it follows from Articles 7 and 17 EEA that acts incorporated into Annex I which concern agriculture and fishery products are binding upon the Contracting Parties.
17. The acts incorporated into Chapter I of Annex I contain provisions on veterinary issues which set out requirements for, inter alia, animal diseases, animal welfare and hygiene of products of animal origin. These acts harmonise the conditions for live animals and the production of products of animal origin, allowing them to be marketed on the internal market.
18. As regards the scope of the EEA Agreement for agricultural and fishery products, the EFTA Court noted in Case E-17/15 *Ferskar kjötvörur ehf v the Icelandic State* that certain legal acts dealing with specific aspects of trade in agricultural and fishery products have been incorporated in the EEA Agreement and that this extension of the scope of the EEA is intended to further a continuous and balanced strengthening of trade and economic relations between the Contracting Parties in a homogeneous and dynamic EEA.⁷
19. The Regulation, which covers both terrestrial and aquatic animals and their products, is incorporated into Chapter I of Annex I and, based on the above, is therefore binding in its entirety and fully applicable to Norway.⁸ This is uncontested in the present case.
20. The Request in essence concerns whether the rules of the Regulation preclude the competent authorities of the EEA States from prohibiting movement of aquaculture animals between establishments within their national borders, when a specific

⁶ Case E-12/16 *Marine Harvest*, [2017] EFTA Ct. Rep. 807, paragraph 65

⁷ Case E-17/15 *Ferskar kjötvörur ehf*, [2016] EFTA Ct. Rep. 4, paragraph 44

⁸ See Case E-17/15 *Ferskar kjötvörur ehf*, [2016] EFTA Ct. Rep. 4, paragraph 47.

assessment has found that consideration of fish health at the individual site or in an area warrant such a restriction even in the absence of disease confirmation, or to refuse an operating plan entailing such movements.

21. An aim of the Regulation, as elaborated in recitals (8) and (9), is to implement the commitments and visions that were set out in the Commission's "Animal Health Strategy (2007-2013) where 'Prevention is better than cure'", in a single legal framework where there was greater emphasis on preventative measures, disease surveillance, disease control and research, to reduce the incidence of animal diseases and minimise the impact of outbreaks when they do occur. The provisions of the Regulation must therefore be interpreted in light of this aim.
22. The question the Referring Court requests the EFTA Court to answer is whether the Regulation precludes the *Member States' central veterinary authorities* from *prohibiting* the movement of farmed fish within their national border or whether the said authorities are *precluded from refusing to approve* an operating plan for an aquaculture establishment. Hence, the question seems to concern whether such *decisions* by the authorities would be in breach of the Regulation. However, on page 4 of the Request the Referring Court formulates the question as to whether the Norwegian legal basis for the decisions (Section 40 of the Regulation on aquaculture operations and Section 19 of the Food Act) is contrary to the Regulation. Similarly, on page 5 of the Request the question is formulated as "whether the Member States *may adopt national rules* allowing the central veterinary authority to prohibit movement of farmed fish [...] or refuse approval of an operating plan [...].
23. At the outset, ESA notes that there could be a difference between, on the one hand, whether a decision by a national authority is in breach of the Regulation, and on the other, whether an EEA State may adopt national rules allowing for such a decision. For the purposes of the present case, ESA notes that Article 269 of the Regulation concerning Additional or more stringent measures by Member States refers to "measures that are additional to, or more stringent" those laid down in this Regulation.

24. Furthermore, ESA recalls that the obligation of Member States to comply with EU law is binding on all their authorities.⁹ ESA submits that the same must apply to all authorities of an EEA EFTA State as regards EEA law, in this case the Regulation as incorporated and implemented into the Norwegian legal order.
25. Based on this, ESA considers that it does not matter for the purposes of replying to the question from the referring court if the present case is assessed from the perspective of the decisions of the *central veterinary authorities* or that of the legal basis for those decisions and will propose answers to the questions as referred to the EFTA Court.¹⁰
26. In ESA's view, the referred question in fact raises two distinct questions, which will be dealt with separately in the following: (1) Whether the provisions of the Regulation preclude the EEA States' central veterinary authorities from prohibiting movement of aquaculture animals between establishments within their national borders. (2) Whether the provisions of the Regulation preclude the EEA States' central veterinary authorities from refusing the approval of an operating plan for an aquaculture establishment, based on movement of aquaculture animals between establishments within their national borders.

4.2 Analysis

4.2.1 Prohibiting the movement of aquaculture animals between establishments

27. ESA considers that the first part of the question on whether the provisions of the Regulation preclude the EEA States' central veterinary authorities from prohibiting movement of aquaculture animals between establishments within their national borders when there is no detected disease or concrete suspicion of disease, should be answered based on Article 269 of the Regulation.
28. Article 269 is part of Title III of Part VIII of the Regulation, which concerns EEA States's measures. Points (a) and (d) of Article 269(1) set out that in addition to other provisions of the Regulation which allow the EEA States to adopt national measures, the EEA States may apply within their territories measures that are additional to, or more stringent than, the measures laid down in Articles 10-17 of

⁹ Case C-204/21 R Commission v Poland, EU:C:2021:878, paragraph 54.

¹⁰ Request Part 7.

the Regulation, which includes additional requirements for biosecurity¹¹ and management measures imposed on operators under Article 10; and the measures laid down in Articles 172-190, which includes additional requirements for approval of establishments under Article 181.

29. Recital 165 of the Regulation states that the Member States should be allowed or encouraged to apply additional or more stringent national measures for animal health, provided that national measures do not compromise the animal health objectives set out in the Regulation and are not inconsistent with the rules laid down therein.¹² Based on the wording of Article 269, read in light of Recital 165, ESA submits that the Regulation does not exhaustively harmonise the measures for animal health available to the EEA States.
30. This is further supported by the explanatory memorandum accompanying the Regulation when it was proposed to the co-legislators. There, under the heading of 'Proportionality', the Commission described the Regulation as follows: *"The Animal Health Law establishes a general framework for the prevention, control and eradication of animal diseases. This framework is built on outcome-based rules, avoiding over-prescriptiveness, and leaving room for MS to regulate or set more detailed legislation when necessary, so providing for the flexibility to adapt the rules to national, regional or local circumstances."*¹³
31. Article 269(2) sets out the criteria which the national measures taken pursuant to paragraph 1 must fulfil. These criteria must respect the rules laid down in the Regulation, and are not to hinder movement of animals and products between EEA States or be inconsistent with the rules referred to in paragraph 1.
32. ESA submits that Point (a) of Article 269(1), which refers to *inter alia* Point (b) of Article 10(1), must be interpreted as allowing the EEA States to impose stricter requirements regarding the biosecurity measures imposed on operators related to

¹¹ 'biosecurity' as defined in Article 4(23) of the Regulation means: *the sum of management and physical measures designed to reduce the risk of the introduction, development and spread of diseases to, from and within:*

(a) *an animal population, or*

(b) *an establishment, zone, compartment, means of transport or any other facilities, premises or location;*

¹² As regards the relevance of preambles/recitals, see Case E-14/11 DB Schenker v EFTA Surveillance Authority, [2012] EFTA Ct. Rep. p. 1178, paragraph 115. See also Case E-16/11 EFTA Surveillance Authority v Iceland, [2013] EFTA Ct. Rep. p. 7, paragraph 122.

¹³ COM(2013) 260 final, page 6.

the specific risks involved for the kept animals and products under their responsibility, taking into account the geographical location and climatic conditions and local circumstances and practices. Such biosecurity measures may include conditions for movement *based on the risks involved*, see Point (b)(iii) of Article 10(4).

33. Hence, Point (b) of Article 10(1), and consequently Point (b)(iii) of Article 10(4), therefore set out criteria for a risk-based approach to establishing the necessary biosecurity measures to prevent the spread of disease, based on the risks involved, and do not restrict these measures only to be taken in case of an outbreak or a confirmed infection. As regards the scope of the possible risks involved, ESA notes that Recital 20 of Regulation identifies several risk factors for the transmission of animal diseases other than direct contact between animals, such as water and air systems, transport vehicles and equipment, and recognises that effective disease controls need to cover all paths of infection.

34. In ESA's view, this implies that measures prohibiting the movement of farmed fish could be compatible with Article 269 where the veterinary authority, following a case-by-case assessment, taking into account all relevant information, has found that considerations of biosecurity warrant such a prohibition. This could be the case also where there is no detected disease or concrete suspicion of disease in the fish. However, in ESA's opinion, an alleged risk would need to be backed up with evidence, and there could not be a *de facto* total prohibition based solely on general reference to the precautionary principle. As is stated in recital 15 of the Regulation "*the risk assessment on the basis of which the measures under this Regulation are taken should be based on the available scientific evidence and undertaken in an independent, objective and transparent manner.*"

35. As regards the requirement of Article 269(2) that the national measures taken on the basis of paragraph 1 respect the rules of the Regulation, ESA notes that the rules concerning the movement of aquaculture animals are laid down in Articles 191-192 of the Regulation. These provisions specify the requirements that operators must adhere to. Implicitly, this presupposes that such movements of aquaculture animals by the operators are in fact authorised. ESA therefore submits that a national measure restricting the movement of aquaculture animals taken on the basis of Point (a) of Article 269(1), referring to Point (b) of Article 10(1) and Point

(b)(iii) of Article 10(4), would not be inconsistent with requirements on operators regarding authorised movements of aquaculture animals.

36. Based on this, ESA submits that national measures that restrict the movement of animals within the territory of the EEA State are compatible with Article 269, in so far as the measures taken are not inconsistent with the rules referred to in paragraph 1 and respect the rules laid down in the Regulation.

37. First, it is undisputed that the present case only concerns measures restricting the movement of farmed fish within the territory of Norway.

38. Second, ESA submits that a national measure prohibiting the movement of farmed fish from one aquaculture establishment to another is consistent with the rules referred to in Article 269(1) as long as it is based on case-by-case assessment of the risks involved and backed up with evidence.

39. Consequently, ESA submits that the Regulation does not preclude national measures restricting the movements of aquaculture animals between establishments within the national borders when there is no detected disease or concrete suspicion of disease, provided that the national measures fulfil the requirements of Article 269, interpreted in light of the objectives set out in the recitals.

4.2.2 Refusal to approve an operating plan

40. In response to the second part of the question on whether the provisions of the Regulation preclude the EEA States' central veterinary authorities from refusing the approval of an operating plan for an aquaculture establishment, based on movement of aquaculture animals between establishments within their national borders, when there is no detected disease or concrete suspicion of disease, but the veterinary authority, following a specific assessment, has found that considerations of fish health at the individual site or in an area warrant such a refusal, ESA considers that the relevant legal basis is Article 181 and Point (d) of Article 269(1), which *inter alia* refers to Article 181.

41. ESA notes that Section 40 of the national regulation on the operation of aquaculture facilities requires aquaculture establishments in seawater to have an operating plan in place at all times, which describes the application of certain additional biosecurity measures as they are defined in Section 40. It can therefore be understood that the

approved operation of aquaculture establishments in seawater is contingent on the approval by the national authorities of these additional biosecurity measures.

42. As set out above, pursuant to Point (d) of Article 269(1) the EEA States may apply measures within their territories that are additional to, or more stringent than, the measures laid out in Article 181 on the granting of, and conditions for, approval of aquaculture establishments. ESA notes that such national measures must fulfil the requirements of Article 269(2), but that this does not, with reference also to Point (b) of Article 10(1) and Point (b)(ii) of 10(4)(b), preclude additional requirements regarding the movement of animals within the national territory.
43. ESA observes that Points (a)(i), (b)(i) and (c) of Article 181 oblige the competent authorities to only grant approval to aquaculture establishments where the establishments comply with the requirements pursuant to Article 10(1)(b), and, that do not pose an unacceptable risk as regards the spread of diseases, taking into account the risk-mitigation measures in place.
44. ESA submits that Article 181 must be understood to impose an obligation on the competent authorities to refuse the approval of establishments where, the biosecurity measures of the establishment are not considered to fulfil the requirements of Point (b) of Article 10(1), including measures regarding the movement of animals, or, where the authorities have assessed that the approval of the establishment poses an unacceptable risk as regards the spread of animal diseases. ESA concludes that this obligation assumes an assessment of the acceptable risk by the competent authorities of the spread of diseases and is not contingent upon a confirmed outbreak or suspicion of disease. ESA notes that such an assessment of the acceptable risk must, in light of Recital 15 of the Regulation, be based on available scientific evidence and undertaken in an independent, objective and transparent manner.
45. Based on this ESA submits that the Regulation does not preclude the competent authorities from refusing an operational plan for an aquaculture establishment, following an assessment of the risk inferred for the spread of animal diseases at the individual site or area, even in the absence of detected disease or concrete suspicion of disease.

5 CONCLUSION

Accordingly, ESA respectfully submits that the Court should answer the question of the Referring Court as follows:

The Regulation is to be interpreted as allowing that the Central Competent Authorities in the EEA States to prohibit the movement of farmed fish from one aquaculture establishment to another one within national borders, or from refusing to approve an operating plan for an aquaculture establishment, in a situation:

- *where there is no detected disease or concrete of suspicion of the disease in the fish,*
- *but the competent authority, following an individual assessment backed up with evidence, has found that considerations of fish health at the individual site or in an area warrant such prohibition or refusal.*

Kyrre Isaksen

Sigrún Ingibjörg Gísladóttir

Melpo-Menie Josephides

Agents of the EFTA Surveillance Authority